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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,864	06/07/2005	Jeanine D Mattson	AH01646K	8020

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
08/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,864	MATTSON ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 32-42, drawn to an isolated nucleic acid molecule encoding a polypeptide comprising sequence of SEQ ID NO:2, isolated nucleic acid molecule comprising the nucleic sequence of SEQ ID NO:1, vector, host cell and method of producing a canine receptor activator of NF-kB.

Group II, claim(s) 6-24, drawn to an immunogenic composition and vaccine composition comprising a canine receptor activator of NF-kB.

Group III, claim(s) 25 and 26, drawn to an antibody or antibody fragment.

Group IV, claim(s) 27 and 28, drawn to a method for inhibiting canine receptor activator of NF-kB ligand activity comprising administering an antibody to a mammal.

Group V, claim(s) 29-31, drawn to a method for inhibiting receptor activator of NF-kB ligand activity comprising administering a receptor activator of NF-kB ligand immunogenic composition to a mammal.

Group VI, claim(s) 43, drawn to a method for inhibiting receptor activator of NF-kB ligand activity in a mammal, comprising administering to the mammal a nucleic acid vector.

Group VII, claim(s) 44 and 45, drawn to a stable cell line.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons: Claims 6-8 do not constitute a special technical feature as it does not define a contribution over the prior art. Claims 6-8 are anticipated by Anderson et al., U.S. Patent No. 6,017,729. Anderson et al. teach fragments of canine receptor activator of NF-kB. See Appendix A. As the inventions do not make a contribution over the prior art, unity of invention is lacking and restriction is appropriate.

The special technical feature of Group I is the isolated nucleic acid molecule encoding a polypeptide comprising sequence of SEQ ID NO:2, isolated nucleic acid molecule comprising the nucleic sequence of SEQ ID NO:1, vector, host cell and method of producing a canine receptor activator of NF-kB. The special technical Group II is the immunogenic composition and the vaccine composition comprising a canine receptor activator of NF-kB. The special technical feature of Group III is the antibody or antibody fragment. The special technical feature of Group IV is a method for inhibiting canine receptor activator of NF-kB ligand activity comprising administering an antibody to a mammal. The special technical feature of Group V is a method for inhibiting

receptor activator of NF-kB ligand activity comprising administering a receptor activator of NF-kB ligand immunogenic composition to a mammal. The special technical feature of Group VI is a method for inhibiting receptor activator of NF-kB ligand activity in a mammal, comprising administering to the mammal a nucleic acid vector. The special technical feature of Group VII is a stable cell line.

Groups I-III and VII are directed to unrelated products. Groups I-III, VII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Groups I-III, VII have completely different structures, being made up of completely different building blocks. These very diverse structures result in completely different modes of operation and modes of function and effects. The nucleic acid of Group I can be used in hybridization assays or to express polypeptides, a function that none of the products of Groups II, III and VII share. The polypeptide of Group II may be used in far-western assays or to make antibodies, a function that none of products of Groups I, II and VII share. Similarly, the antibody of Group III can be used to isolate/detect the polypeptide of Group II, a function that none of the other products share. The stable cell line of Group of VII can be used to propagate expression vectors, a function that none of the products of Groups I-III share.

Groups IV-VI are directed to unrelated methods. Group IV requires administering an antibody to a mammal, which is not required or accomplished by the method steps of the other Groups. Group V requires administering a receptor activator of NF-kB ligand immunogenic composition to a mammal, which is not required or accomplished by the

method steps of the other Groups. Group VI requires administering to the mammal a nucleic acid vector, which is not required or accomplished by the method steps of the other Groups. The instant specification does not disclose that these methods would be used together and all are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs these functions using a structurally and functionally divergent material. For these reasons the Groups IV-VI are patentably distinct.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: additional elements of the immunogenic composition.

Applicant is required to elect one species of the additional elements of the immunogenic composition:

(a) a foreign T helper lymphocyte epitope.

(b) an element that targets the canine receptor activator of NF-kB ligand immunogenic composition to an antigen presenting cell or a B-lymphocyte,

(c) an element that stimulates the immune system, and

(d) an element that optimizes presentation of the canine receptor activator of NF-kB ligand to the immune system.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claims 9, 12, 13, 14, 15, 16, 17, 18, and 19.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species comprise distinct sequences because they are composed of unrelated or diverse sequences, different coding regions and/or imparts structural and functional differences.

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the

limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Applicant is advised that the reply to this

requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, the search requires a different non-patent literature search due to each group comprising recognized divergent subject matter, different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
8/10/07

/Gary B. Nickol/
Supervisory Patent Examiner, Art Unit 1646